UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 22, 2015

J. Michael Kelly
Agent/Authorized Representative Toxcel, Inc.
DRS Laboratories Inc.
7140 Heritage Village Plaza
Gainesville, VA 20155

Subject: Protocol Review – Efficacy Protocol for Sodium Chlorite Technical
EPA Protocol Identifier: 90094-1
Application Date: April 1, 2015
Decision Number: 502955

Dear Mr. Kelly:

The protocol submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, has been reviewed. Please see the attached review dated July 20, 2015.

Please note that the Agency's review of this protocol is considered complete. Any future submissions related to this protocol must be submitted under the appropriate PRIA category.

If you have any questions, please contact Ben Chambliss by phone at (703) 308-8174, or via email at chambliss.ben@epa.gov.

Sincerely,

Demson Fuller, Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: efficacy review

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July 20, 2015

MEMORANDUM

Subject: Protocol Review for Sodium Chlorite Technical; EPA Reg. # 90094-1; DB Barcode: D427009.

From: Ibrahim Laniyan, Ph.D.
Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Mark Perry
Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Demson Fuller, RM 32 / Benjamin Chambliss
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: DRS Laboratories, Inc.
450 Allentown Drive
Allentown, PA 18109

I. BACKGROUND

DRS Laboratories is submitting a testing protocol to develop efficacy data that will support the use of the product, Sodium Chlorite Technical (EPA Reg. no. 90094-1) to generate gaseous Chlorine dioxide for use in the registrant's Mini-CD System® to decontaminate Biological Safety Cabinets (BSCs). Protocol was developed by DRS Laboratories and Azzur Labs.

This data package is identified as D427009 contained a letter from the applicant representative to EPA (dated April 1, 2015), one protocol (MRID 496056-01) that have been revised under MRID # 496749-01 (dated July 15, 2015).

II. BRIEF DESCRIPTION OF THE PROTOCOL

1. MRID 496056-01 "Proposed Protocol to Support Use of EPA Reg. No. 90094-1 with the Mini Chlorine Dioxide System (MCS) to Sterilize/Decontaminate Confined Areas, Specifically Including Biological Safety Cabinets" by Michael Regits - DRS Laboratories Inc.

The purpose of this proposed study is to satisfy EPA Guideline 810.2100 as required to support the amendment of EPA Reg. No. 90094-1 to include use as a sterilant in confined spaces when applied using the DRS Laboratories' (DRS's) Mini Chlorine Dioxide System® (MCS) as directed.

Method References:

1. *Official Methods of Analysis of the AOAC International*, Chapter 6, Disinfectants, Official Method 966.04 Sporicidal Activity of Disinfectants, Current edition. AOAC International, Suite 500, 481 North Frederick Avenue, Gaithersburg, MD 20877-2417.
2. *Official Methods of Analysis of the AOAC International*, Chapter 6, Disinfectants, Official Method 2008.05 Quantitative Three Step Method (Efficacy of Liquid Sporicides Against Spores of *Bacillus subtilis* on a Hard Nonporous Surface), Current edition. AOAC International, Suite 500, 481 North Frederick Avenue, Gaithersburg, MD 20877-2417.
3. *Annual Book of ASTM Standards*, Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides, Designation E 2197. American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428, current edition.

Test System (Microorganism):

1. *Bacillus atrophaeus* (ATCC #9372)
2. *Geobacillus stearothermophilus* (ATCC #7953)

Each on two types of surfaces, stainless steel discs (representing hard non-porous surfaces) and cellulose (representing porous surfaces), as biological indicators (BIs).

Procedure:

1. Use a Baker SterilGard® III Advance Biological Safety Cabinet, Model SG:603, which has a total volume of 78 ft^3.
2. Introduce a humidity source, temp / humidity meter, and biological indicators are placed within the enclosure to be decontaminated (28 locations).

3. Seal enclosure and incorporate into the seal a gas inlet and outlet port for use with the MCS.
4. After appropriate humidity (i.e., within 60% to 70% RH) and temperature (i.e., within 59°F to 75°F) are confirmed, Chlorine Dioxide (CD) is produced and released and the decontamination cycle begins.
5. Generation efforts shall be taken to generate the maximum CD gas concentration of 0.13 g/ft3, not to exceed this value. Generation will be performed with the three sets of Part "A" and "B" and when the value of 0.13 g/ft^3 of CD is met, the CD generation shall cease and recirculation shall continue. The duration of the decontamination period will be a fixed time of 90 minutes.
6. After a treatment period of 90 minutes, CD gas is removed from the enclosure (~ 45 minutes) using the MCS's "scrubbing cycle", to 0.1 ppm.
7. After all the BI's are processed into the neutralizing subculture media tubes, they will be transported to the Azzur laboratory, by Azzur to be placed in the appropriate temperature incubators.

Success Criteria.

- Zero growth per 60 carriers
- Biological Indicators must yield a population of at least 1.0 x 10^6.
- Neutralization must be confirmed
- For the positive control, both unexposed controls for each lot of biological indicator used must be turbid (positive). For the negative control, the unopened tube of TSB must be clear (negative).

III. CONCLUSION AND COMMENTS

1. The submitted protocol (MRID # 496749-01) **is adequate for testing** decontamination of BSCs.

2. It is a reminder that product must be tested at the lowers effective concentration of 0.13 g/ft^3 (4.7 g/m^3).

3. The potential variability in the method must be addressed prior to data generation. The Agency encourages the testing laboratory to assess the degree and sources of variability introduced by any significant method modification – this information should be supplied to the Agency prior to GLP testing. For example, preliminary runs of the study should be performed to determine the degree of variability associated with control and treated carriers; the number of carriers should be increased if the variability is too high.

4. The study controls must perform according to the criteria detailed in the protocol. If any of the control acceptance criteria are not met, the test may be repeated.

5. Provide a list of any deviation or modification to a standard method.